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PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: D. Kempf, et al.

Serial No.: 10/802,829

Filed: March 18, 2004

Title: A METHOD FOR TREATING A DISEASE,  
DISORDER OR ADVERSE EFFECT CAUSED BY  
AN ELEVATED SERUM CONCENTRATRATION  
OF AN UGT1A1 SUBSTRATE

Group Art No.: 1614

Examiner: (not yet assigned)

Case No.: 7050.US.02

Date: November 17, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Certificate of Mailing under 37 CFR §1.8(a):**

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Date of Deposit: November 23, 2004

Wanda E. Smith  
Wanda E. Smith

**TRANSMITTAL LETTER**

Dear Sir:

Enclosed herewith for the patent application identified above entitled A METHOD FOR TREATING A DISEASE, DISORDER OR ADVERSE EFFECT CAUSED BY AN ELEVATED SERUM CONCENTRATRATION OF AN UGT1A1 SUBSTRATE, Serial No. 10/802,829 and filed on March 18, 2004, are the following:

1. Information Disclosure Statement;
2. Form PTO 1449, in duplicate;
3. References as cited on PTO 1449
4. Copy of International Search Report and
5. Return Receipt Postcard.

The Commissioner is hereby authorized to charge any additional Filing Fees required under 37 CFR §1.16, as well as any patent application processing fees under 37 CFR §1.17 associated with this communication for which full payment had not been tendered, to Deposit Account No. 01-0025.



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Respectfully submitted,  
Kempf, et al

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Registration No. 45,805  
Attorney for Applicants



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**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed, to the knowledge of the undersigned, before the mailing date of a first Office Action on the merits. Enclosed also is a copy of the PCT International Search Report dated August 9, 2004 (conducted by the ISA/EP) in corresponding International Application No. PCT/US 2004/008415, in which references were cited. Applicants respectfully petition and request that the Examiner consider the listed documents and evidence such consideration by making appropriate notations on the attached form. Copies of the listed documents are attached.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

The Commissioner is authorized to charge our Deposit Account any additional fees (or credit any over payments) that may be required under 37 C.F.R. §§ 1.16 and 1.17 in association with this communication for which full payment has not been tendered.



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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE  
(Modified) PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

(37 CFR 1.98 (b))

ATTY. DOCKET NO.

7050.US.02

SERIAL NO.

APPLICANT(S)

Kempf et al.

FILING DATE

March 18, 2004

GROUP

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	ISSUE DATE	INVENTOR	CLASS	SUB CLASS	FILING DATE
A1	6,037,137	03/14/2000	Kempf et al.			06/26/1996

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

DOCUMENT NUMBER	PUBLIC-ATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANS- LATION YES NO

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

C1	Agarwala et al., "Steady state pharmacokinetic (PK) interaction study of Atazanavir (ATV) with Ritonavir (RTV) in healthy subjects," Poster presented at the 42 <sup>nd</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, San Diego, CA, September 27-30 <sup>th</sup> , 2002
C2	O'Mara et al., "Relationship between uridine diphosphate-glucuronosyl transferase (UDP-GT) 1A1 Genotype and total bilirubin elevations in healthy subjects receiving BMS-232632 and saquinavir," Poster presented at the 40 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto, Ontario, Canada, September 17-20, 2000
C3	Zucker et al., "Mechanism of indinavir-induced hyperbilirubinemia," PNAS 98(22):12671-12676 (2001)
C4	Ritter, Joseph K., "Expression and inducibility of the human bilirubin UDP-glucuronosyltransferase UGT1A1 in liver and cultured primary hepatocytes: Evidence for both genetic and environmental influences", Hepatology, Vol. 30, No. 2, Aug. 1999 (1999-08), pp 476-484
C5	Sugatani, Junko, et al, "The Phenobarbital response enhancer module in the human bilirubin UDP-glucuronosyltransferase UGT1A1 gene and regulation by the nuclear HEPATOLOGY", Vol. 33, No. 5, May 2001-05, pp 1232-1238
C6	Baede, P., et al, "Drug interactions with TMCT25, a potent next generation NNRTI". ABSTRACTS OF THE INTERSCIENCE CONFERENCE ON ANTIMICROBIAL AGENTS AND CHEMOTHERAPY, Vol. 42, 2002, page 27 & AMERICAN SOCIETY FOR MICROBIOLOGY (ASM) Annual Meeting on Infectious Disease; San Diego, CA, USA; Sept. 27-30, 2002 abstract
C7	Penzak, Scott, et al., "Influence of ritonavir on olanzapine pharmacokinetics in healthy volunteers", Journal of Clinical Psychopharmacology, Vol. 22, No. 4, August 2002, pp 366-370
C8	Ouellet Daniele, et al, "Effect of ritonavir on the pharmacokinetics of ethinyl oestradiol in healthy female volunteers", BRITISH JOURNAL OF CLINICAL PHARMACOLOGY, Vol. 46, No. 2, August 1998, pp 111-116

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.